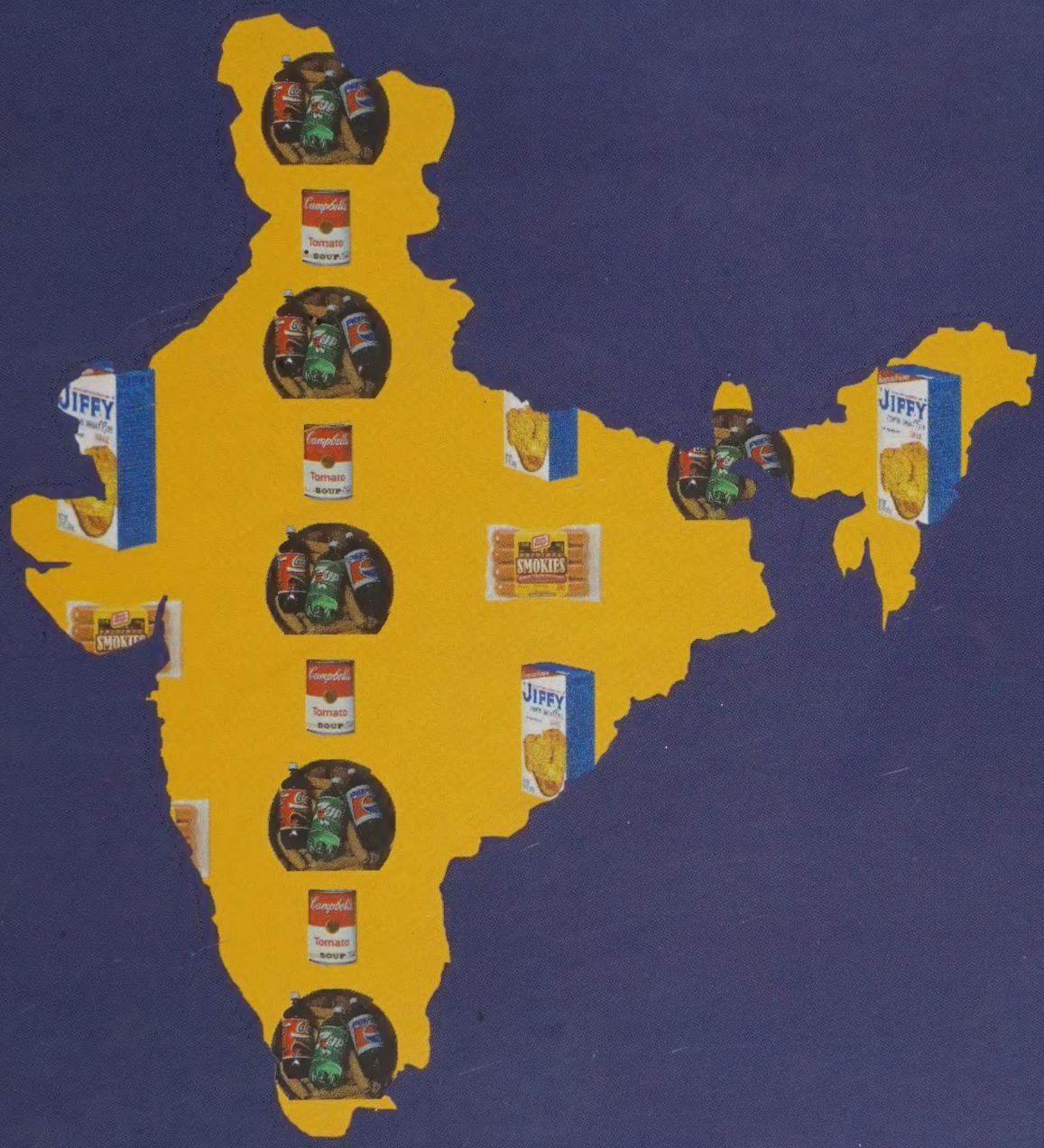
Analysis of The Indian Food Control System: Adequacy of The PFA Act

-Robert J. Scheuplein



Agriculture Commercialization & Enterprise Project

- A USAID Funded Activity

New Delhi. August 1, 1997

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Background

The task under this project was to evaluate the adequacy of the current PFA Act (1994 Prevention of Food Adulteration Act), the major piece of national food safety legislation supporting the food-control system in India. More specifically, I was asked to comment on a Task Force Report which made certain modifications or Amendments to the act. This Report, "Rationalisation of the Food Act : Report of the Task Force on the Food Laws", January 1996, was prepared in response to perceived long-standing problems with the PFA. These problems were primarily those perceived by Indian food industries.

As I studied the PFA Act and the proposed changes suggested by the Task Force, it became clear that only by understanding the actual operation of the food-control system in India, could I meaningfully evaluate the proposed statutory changes. The reasons are reasonably straightforward. The PFA Act is the legal underpinning for the food-control system; it outlines its goals and enforcement objectives and establishes the central Food laboratories and their functions. The PFA Act and its accompanying rules also authorise and define the responsibilities and duties of public analysts and food inspectors. Only by seeing and understanding the actual operation of this system can the effectiveness of the statutory provisions be evaluated.

Accordingly I spent several weeks in India interviewing small food manufacturers and processors, representatives from multinational corporations, private experts in the PFA Act, government officials in state laboratories, central laboratories and in the ministries, importers, exporters and members of industry trade associations. What I learned convinced me that while the PFA Act is a vital part, it is only a part of the food-control system in India. Changes in the PFA Act itself or in the rules, without corresponding changes in the other parts of the food-control system can have very little effect in either improving the safety of the food-supply or reducing regulatory barriers for industry. For this reason, my report will focus on the Indian national food-control system and my comments on the PFA Act will be considered in the overall context of the needs of the whole system.

By the "food-control system" I mean the municipal, state and national organisations involved in either the regulation, inspection or analysis of food and food agricultural products together with their supporting legislation and rules. This includes the local food inspectors, the public analysts both at the municipal and state level, their laboratory facilities, the four central food laboratories designated in the PFA Act and the PFA division in Delhi. In addition to the Prevention of Food Adulteration Act, or the PFA Act, other national laws impact food control. These are principally, the Essential

Commodities Act, 1955; the Standards of Weights and Measures Act, 1976; the Consumer Protection Act, 1986; Agricultural Marketing Produce (Grading and Marketing) Act, 1937; The Indian Standard Institution Certification Mark Act, 1952 as amended, and the Bureau of Indian Standards Act, 1986

Introduction

The majority of the Indian population, approximately 70%, live in rural areas and depend almost totally on raw/fresh home-cooked, agricultural produce. A similarly large percentage of the urban population subsist on home-cooked produce, on "street food", or on food from local eateries and on food supplied from small independent producers. This large unorganised, small independent producer sector serves the poor and the lower middle classes. It is by far the larger food sector. The richer people patronise the better restaurants and eat packaged and processed food and food of better quality. Only a small percentage of the Indian population consumes processed food and a far smaller percentage consume processed-packaged food (~5%). However, this last segment consists of tens of millions of reasonably well-off consumers and is rapidly growing. It is the target market for major growth in the commercial food sector.

The size of the food industry in India is enormous. It is Rs 250,000 crore or approximately 75 billion dollars, and accounts for 26% of the GDP. This makes it far larger than the entire manufacturing sector. India's population is forecast to grow by 54 crore (540 million) by the year 2,030, reaching over 150 crore (1.5 billion) people. The food industry is forecast to be one of the major growth areas in India in the years ahead (McKinsey Report, Nov 27, 1996).

The PFA Act like national food legislation in most countries, is targeted at food in commerce, i.e. processed food, not home-cooked food. The PFA Act is an amalgam of English common law and US food statutes and is a fairly modern food law. This is not to say that all of its provisions are up-to-date. Because of this focus and the large unprocessed food sector in India, the provisions in the PFA Act are today largely irrelevant to the safety of the food consumed by the majority of the Indian population.

The large dependence on home-cooked foods and the presence of a large number of "street vendors" and small, family-sized or slightly larger, food processing operations is typical in India. The owners and operators of these small firms tend neither to have the knowledge of proper hygiene practices nor much concern about it. This sector is a major source of food contamination as indicated by studies by FAO and the central Food laboratories at Pune and Calcutta. A major problem is the infrastructure in the food area. Many food processing plants in the rural areas don't have a clean water supply or proper waste disposal. The equipment many producers use is old and difficult to keep clean. Being a tropical country, microbial contamination is accentuated by high ambient humidity and temperature. There is also a large manual contribution to the preparing and processing of foods, poor standards of hygiene and sanitation, poor garbage

disposal, and the use of unsafe water. These facts needs to be remembered when reforms of the food-control system are suggested. Sanitation and educational programs are badly needed to improve food safety and nutrition for the unorganised food sector. These programs could be put in place by the states and local communities authorities, but some leadership needs to be taken at the national level.

These different food sectors, the large population growth rate, the different sub-populations and eating habits, and the tropical climate, the lack of sanitation in many areas, and the poor water quality, make the government's responsibility to assure the safety and quality of the Indian food supply a major technical and administrative challenge. It is important to ask how well the current food laws and their implementation serve the varied needs of the Indian public.

Modern government controls related to food quality and safety generally have three objectives: (1) to assure a safe, wholesome food supply and an acceptable level of consumer nutrition. (2) to foster (or at least not impede) innovation and variety in the food supply (3) to facilitate the necessary growth and commerce in food products, including exports.

The first objective is primary and often the only one specifically mentioned in statutes. But the others are present, either in the basic need to have and preserve a food supply, in the need for jobs, in the omission of draconian standards, in provisions for due process, and in the recognized day-to-day need to consult with industry. The perceived importance of these three basic objectives have shifted over the years as India has successfully passed through several internal crises and as India's policies have become more outward looking. The food control system has not quite kept pace with these changes. It has now become essential to pay attention to the facilitation of the export of agricultural and food products. The Sanitary and Phytosanitary (SPS) agreements and the new World Trade Organisation have indicated the path to follow to achieve ready acceptance in world markets. The SPS agreements call upon members to harmonise their sanitary and phytosanitary measures with international standards (Codex Alimentarius Standards). For food safety, the SPS agreement requires harmonisation of food standards, food additive ADIs, pesticide and animal drug residues, contaminant tolerances, methods of analysis and sampling and codes and guidelines for hygienic practices. So far, India has given little attention to these matters.

Measured by any one or all of the above objectives, the current food control system in India does not adequately serve the needs of the public. The food control system barely meets, if it does meet, the most basic food safety goal, to provide a safe and nutritional food supply for the Indian people. The contamination of the water supply by faecal coliforms is essentially total, once one is away from the sites of water purification plants in the major cities. There are virtually no effective national monitoring or surveillance programs providing information on food contamination, food borne diseases or on food quality. The food standards in the PFA and the FPO (Food Product Orders) are often burdensome to industry without having a discernible public

benefit. It is very difficult, time consuming and frustrating to get changes made to the rules, e.g., food standards, and when changes are made, it is often without adequate notice to the industry. The inspection programs, both of the PFA and the FPO are weakened by corruption and bribe taking. In addition both sets of standards, PFA and FPO, are largely out of date.

It is important to keep in mind that India's resources are limited and any proposed solution to the present shortcomings with the food-control system that entail large continuing expenses, at least in the immediate future, are impractical. Laboratory instrumentation in India is relatively expensive, most scientific instruments (e.g. those needed for the chemical analysis of foods) are imported from United States, Europe or Japan. On the other hand, labor in India, including professional labor is relatively cheap, barely 1/10-1/20 of the cost of that in western countries. India's large educated labor force is a major strength and it should be taken advantage of in any plan to improve the system.

I. Historical Background

Prior to 1954, food authority in India was local, in the form of local provincial acts. The national law, The Prevention of Food Adulteration Act or PFA Act was enacted in 1954. The PFA Act has been subjected to amendments in 1964, 1971, 1976 and 1986. In 1986, an amendment to the PFA authorized the participation of consumer organizations in the implementation of the act. Of these, the amendments in 1971 were fairly extensive. In 1976, during a period of food shortages and serious law-breaking, the primary food safety law, "The Prevention of Food Adulteration Act" (the PFA) was rigorously strengthened by the closing of loopholes and by the incorporation of severe penalties for violations. The minimum sentence then put into place, and still in the current law, was 6 months in jail. Today these same harsh penalties are archaic, self-defeating and would be silly, if their consequences were not so severe. The existence of these unusual penalties is a major reason for the widespread corruption in the food inspection area and the failure of the law to work effectively..

However, the food law is not the only place where improvements might be made. The organisation and capabilities of the central bureaucracy, the central, state and municipal laboratories also need to be considered..

II. Organisation of the Present Food Control System

A. Organisation at the central level

Section 3 of the 1954 PFA Act provided for the creation of a central Committee for Food Standards (CCFS) to advise the central government and the state governments on the administration of the act and to carry out the functions of the act.

The CCFS shares authority with the central government in the administration of the act. Under Sections 22-A of the act the central government can give directions to the state governments regarding the execution of the provisions of the act. Under Section 23 of the act the central government can make rules to carry out the provisions of the act after consultation with the CCFS.

The CCFS consists of the Director General, the directors of the central food laboratories, representatives from other concerned ministries, one representative from each state and other nominated representatives of consumer, agricultural and commercial interests. Today the CCFS is a 55 member committee which typically meets only once a year.

The CCFS works through a technical staff located in the office of the Director General for Health Services (DGHS). This technical staff, the national/central PFA Division, consists of 27 members and its primary function is to work both as a secretariat for the CCFS and as the principal staff of the central government. The CCFS has constituted 9 sub-committees, but except for labelling and food additives, the other seven have met only 1-3 times during the last five years. The central staff has accumulated many other related duties, including liaison with other government agencies, the Codex Commission and consumer organisations.

B. The Food Inspection System

The PFA Act authorises food inspections and outlines qualifications and duties for food inspectors (Sections 8 and 9). Over the whole of India, approximately 50,000 samples of food are taken annually by local food inspectors for analysis by state and local laboratories. These are taken from food manufacturing plants and from sales operations (distributors, stores, restaurants and vendors). These samples are analysed for microbiological contamination, for the presence of extraneous substances, for pesticide residues and for adherence to standard composition according to the food standards outlined in the PFA Rules. But, unfortunately, all is not well with the inspection system or with the analysis of food samples.

C. The central laboratories

The 1994 PFA Act provided for the creation of one or more central Food laboratories (Section 3). There are now four of these laboratories in: Pune, Calcutta,

Ghaziabad and Mysore. The food-control system envisaged that food inspectors would give samples of food for analyses to public analysts working at laboratories at the municipal or state level. The central Food laboratories were created in part to be the laboratories of last resort in the case of disputes over analysis. The statute permitted defendants to have samples analysed by a central Food Laboratory in case they believed strongly that the results of the public analyst were in error. In addition the central Food laboratories were given the roles of "fixing standards for articles of food" and for "standardising methods of analysis".

D. State and Municipal laboratories.

Today there are 78 municipal or state laboratories. (In some states the municipal are either regional or district laboratories.) These laboratories analyse the bulk of the samples under the PFA Act. Some of the duties and responsibilities of all the state laboratories appear to be indifferently pursued. Some of the state governments appear not to have not even formulated the state PFA Rules, required under the act. The majority of the municipal laboratories are small, under-staffed and under-equipped, and able to perform only the more routine analyses. Microbiological contamination of food rarely is reported, despite the fact that studies carried out by the central laboratory at Pune and Calcutta with the support of FAO have indicated considerable microbiological health hazards from street food.

III. Major Detailed Findings

A. Industry Survey

As the result of several weeks of interviews with various members of the food industry, the following complaints were collected. Each one of these complaints was mentioned sufficiently often so they are, in fact, broadly felt. Some were mentioned by virtually everyone interviewed.

The industry complains of:

On Inspections and Sampling

(1) bribe taking at the inspection level;
(2) unfair targeting of industry segments by inspectors;
(3) lack of consistency in state-to-state sample analysis;
(4) improperly obtained or prepared regulatory samples;
(5) incompetent or outdated FPO inspections;
(6) inadequately trained inspectors;
(7) inadequate guidance given to inspectors on the drawing of regulatory samples

On analysts and analysis:

(8) poor quality of sample analysis by both municipal and state laboratories;
(9) inconsistent methods of analysis from state to state;
(10) poor quality of food analysts at both municipal and state level;
(11) long delays between the taking of a sample and the report of a violation- sometimes a year or longer;
(12) corruption at the state laboratories;

On the PFA Act:

(13) unduly harsh penalties under the PFA for violation of the adulteration provisions;
(14) absence of penalties for dishonest inspectors;
(15) section 13.3 of the PFA Act, is unfair or unworkable;
(16) delays extending for 10-15 years to get court cases resolved;
(17) troublesome definition of adulterant (Section 2(i);

On the PFA Rules:

(18) inconsistent, outdated food standards;
(19) irrational restrictions of food additives in some foods but not others;
(20) multiple inconsistencies between PFA and FPO standards;

On the ministries:

(21) slow movement at the ministerial level to do anything;
(22) too little ministerial focus (funding) on food issues relative to drugs;
(23) an unresponsive bureaucracy: the bureaucracy tends to say: "the responsible official is out", or "we will get back to you later", or " its on the pile to be considered"-in general it tends to "pass the buck";
(24) self-serving resistance to change at the ministries;
(25) inadequate consumer and industry advisory services.
(26) inadequate industry and consumer input to food-standard decisions and other rules;
(27) poor responsiveness at the central level to requests for information and for modifications to standards;
(28) inadequate co-ordination of food-control functions between various ministries.

B. Discussion of Specific Food Issues

1. Food Standards

Delays and complaints over bureaucratic responses are not unique to India. Many of the complaints are familiar to me as a former FDA official. However, there are some problems that are unique to India and are an outgrowth of the current food-control system itself.

Taken together, the emphasis of the PFA rules on food standards and the capacity of the state food laboratories to measure little else than the more routine chemical deviations and "matter out of place", combine to place a great deal of weight on food standards, many of which are of little consequence to health. The law makes it a violation of the adulteration provisions for an article of food to deviate from the standards specified in appendix B of the PFA Rules.

> *" Any article of food which does not conform to the standards specified in Appendix B will be said to be adulterated because the quality or purity of the article falls below the prescribed standard or its constituents are present in quantities which are in excess of prescribed limits. [...] Even when there is marginal deviation from the prescribed standard, the article of food is adulterated. (Section 5, PFA Rules, 1955, Notes.)*

The standards in many cases are very old and are some are essentially arbitrary. It often would make no difference to the quality of the food product or to its nutritional value and none to the safety of the food if some of the standards were unattained or exceeded.

Setting standards of identity for food does have merit, if it is done with thought and discretion. Generally standards in most countries are of two types: (1) those

established to assure that consumers within a country obtain the food product that they have a right to expect from the label declaration on the product, and (2) those intended to facilitate international trade wherein the standard is established to harmonise with international norms. An example of the first type would be the US standard of identity for mayonnaise. The word "mayonnaise" is designated a "common or usual name" and in order to legally place it on a food label, the food must adhere to the standard recipe. The practice goes back to the time when processed foods first appeared in grocery stores in the US. Some unscrupulous manufacturers sold a concoction called "mayonnaise" but it had no eggs or no oil in it. The product not only defrauded the consumers but also made it difficult for honest food suppliers, who could easily be undersold. In order to stop this practice, "standards of identity" were established for those foods that had a widely recognised and anticipated recipe and a "common and usual name". Such standardised foods could carry the "common and usual name"; foods not meeting the recipe had to bear a different name on the label. Even here there could be other ingredients present so long as they were safe and declared on the label. (Recently the FDA floated a proposal that most standards of identity be abolished as no longer necessary given the advances in food technology and the many new varieties of processed food and new ways of making it.)

An example of an international standard could be the any one of the more than 300 Codex standards on virtually every food product in world commerce. For example: for coconut oil the standard is:

Coconut oil shall be the oil derived from the coconut (Cocoa nucifera), and shall have-
(a) a specific gravity ($20^oC./20^oC$) of not less than 0.917 and not more than 0.919.
(b) a refractive index (40^oC) of not less than 1.448 and not more than 1.449.
(c) a saponification value of not less than 248 and not more than 264.
(d) an iodine value (Wijs) of not less and not more than 11.
(e) an acid value of not more than 14.1 mg KOH /gm; and
(f) unsaponifiable matter of not more than 8 g/kg.

These specifications assure the importer that the product is coconut oil of the accepted international quality. They are chemical tests that assure that the product has the right plant origin, has not spoiled, has not been diluted with inferior substitutes and is not burdened with extraneous matter.

It would appear that many of the food standards in the PFA and FPO go needlessly into more detail which would be better left to voluntary standards within the food industry. Appendix 2 gives a list of dozen or so of examples. Many standards will still be desirable, but they should be brought up to date and made to serve only the legitimate purposes of informing the consumer, preventing fraud and facilitating commerce in food stuffs.

Some of the delays food producers have experienced in the ministries, in getting changes to rules approved, probably would not have occurred in other countries because the additives involved would not have required government approval to begin with. In most countries there are lists of ingredients that can be used up to fixed levels without specific government approval. In the US most flavourings and spices can be used in processed foods at the discretion of the food producer, so long as no more is used than is necessary to achieve its purpose. Any color on the list of safe food colors can be used up to fixed limits and there is no restriction on mixing two or more colors together.

2. Food Hygiene Regulations

The PFA Act makes illegal the selling of food with microbial contamination, (Section 2(ia)(e)). However the word "microbial" does not appear in the PFA Act and the risk from microbial hazards in food is very much neglected relative to the chemical hazards. As will be noted more fully below (Appendix 1), Section 2(ia)(e) itself is weak and redundant; since as written, it allows a person to sell, prepare, package , convey, store or display for sale a food under unsanitary conditions. This provision requires a finding of adulteration before a charge can be made. India is perhaps the only country of significance where operating an unsanitary food facility is, per se. permitted.

Hygeine at the Factory Level - The PFA Act does not contain a section on food sanitation or food hygiene. Such regulations appear in the FAO model food law, EC directives and under GMPs in the US CFRs (Code of Federal Regulations). These regulations among other things describe the conditions and restrictions on plant grounds, plant construction, facilities, equipment, utensils and food-contact surfaces, sanitary facilities and controls, general plant maintenance, process controls, health measures, and personnel training necessary to obtain a licence to operate a facility where food is sold, prepared, packed, stored or displayed for sale. In many countries these regulations are enforced by local officials with the co-operation and support of the national government.

The only place hygiene standards appear in Indian rules are in the Food Product Orders under the Essential Commodities Act. For example, the 1995 Fruit Products Order, The Second Schedule, Part I(A) contains 14 sentences outlining sanitary requirements of a factory manufacturing fruit products. These offer very limited instruction, do not prescribe microbial monitoring and would not prevent microbial contamination from occurring nor allow the source of any contamination to be tracked.

A series of HACCP type controls are being instituted in the developed countries and India needs to update it food sanitation controls to conform to them. It needs to be understood that HACCP is not a replacement for adequate sanitary controls, instead HACCP is designed to be built upon them. Adequate attention to sanitation in the form of GMPs (good manufacturing processes) that contain sanitation elements need to be put in place first.

Retail Sanitation - Often the training given to food handlers has been given too little attention both in developed and developing countries. Outbreaks of food poisoning have most often been found to be the result of ignorance of safe handling practices. In a few countries legislators have recognized their importance and have included training requirements in their foods laws or regulations. The 1967 law in Iran specifies that those technically responsible for factories manufacturing foodstuffs must have requisite technical training and experience. Yougoslavia requires that all persons engaged in the manufacture or sale of foods who come into direct contact with food must take courses in personal and food hygiene. Korea requires that restaurants have licensed cooks who have completed courses in designated training agencies.

A further refinement is education in a "Food Code". In the US the FDA has developed a "Food Code" to provide guidelines for the prevention of foodborne illness. The guidelines are aimed at the layman who handles food at the retail level. The Food Code provides definitions, standards and safe operating procedures for the handling of food in retail operations. It contains information on microbiological hazards in food, on how to reduce microbial contamination by proper temperature control and attention to sanitation procedures. It describes those procedures as applied to food handling in restaurants and grocery stores and small vending operations and has ample references for detailed application. Normally instruction in the Food Code is offered by major food outlets as a short, 1 week course for its new personnel. Instruction is also available from local Health officials, from food trade associations or from regional FDA offices.

This kind of instruction would seem to be very valuable for the small scale food sector in India. Priorities should be established, with the highest priority being given to those industries and outlets where the food is most likely to be contaminated in ways that can produce illness.

Some of the local food inspectors could be given instruction in such a Food Code so that they could teach it to local food vendors and small-scale operators. Instead of cultivating a "police" mentality, the food inspectors could become "teachers". It is very likely that many violations of the law are unintentional and arise from ignorance of the importance of good sanitation and safe food-handling practices. In fact when penalties for adulteration are assigned by the courts, mandatory attendance and sucessful completion of such cources of instruction would do far more good for the Indian public than jail sentences for violators.

3. Food Inspection

While this project did not entail any first hand experience with the food inspection service in India, I was able to hear from supervisors about the present conditions at the state laboratory level which works closely with inspectors. In addition, as indicated above, the universal lament from industry, is that the food inspectors take bribes and don't do the job expected of them. If this is true, and I believe it is, since I

have heard it from all parts and all levels of the food industry; it is major fraud perpetrated primarily on the Indian people.

There are two major problems with the current food inspection system. Foremost is the problem of bribes given to inspectors for favourable inspection reports or for not inspecting at all. It appears that quite small sums are involved, estimated at only 2,000-3,000 rupees per year per plant. But, with several dozen plants per inspector, this is enough for an inspector to double or triple his annual salary. It is also appears that as many as half of the inspectors take bribes, so it is not an unusual practice. Prior to 1976 this was not true, the draconian penalties in the PFA Act helped encourage this corruption. The food manufacturer or vendor is faced with the prospect of 6 months in jail or parting with a few rupees. Very few 6-month penalties are handed down. Some major companies have policies forbidding bribes, and these companies like Unilever, Lipton, Nestle find themselves in court fighting charges of adulteration. They rarely lose a court case, but the cases can drag on for several years and consume many man hours. (Unilever and Nestle estimate 100-200 cases involving their companies in process at any time.)

There is another problem with the inspection system that derives indirectly from the bribing. There exists no national annual survey of the types of food plants or sales operations sampled by inspectors. However, there is reason to believe that the segment of the market that needs monitoring most, the small company sector, gets the least effective enforcement. These small manufacturers are the most vulnerable to the bribes and are more willing to pay to keep out of jail. So their operations remain relatively unaffected by the inspections. For reasons cited above, multinational companies and others complain that inspectors unfairly target their operations.

The purpose of the food inspection system and the enforcement of the adulteration provisions is to eventually improve the safety of the food supply. This is done, in theory, by sending a clear signal to the food industry, through regular inspections and sampling, that adulteration of food won't be tolerated. After an inspection, when a fault is found, the hoped-for reaction is that the manufacturer will quickly move to put things right so that he won't be in violation next time. Instead, the message in India is that as long as a bribe is paid, it is all right to adulterate the food. Because of the bribing, the shoddy manufacturer has no incentive to clean up his act. The food-control system involving several thousand individuals and millions of man hours in food analysis and inspection, to say nothing of the health of the nation, is undermined for a few rupees.

The food inspector occupies a key position in a country's food control service. He is in the front line and is the eyes and ears of his agency and must be able to recognise collect and transmit evidence when a violation has occurred. He collects samples for routine or special analysis. He is trained or should be trained to inspect various types of food establishments for compliance with sanitary requirements and hygienic practices. He instructs food handlers and packers in hygienic practices and

good manufacturing practices and encourages voluntary compliance. He investigates consumer complaints about the safety and unfitness of foods and other violations of the laws. He works with other officials, prepares cases for trial and testifies in court. He often participates in consumer education. If reliable inspectors, capable of doing these things, are to be recruited and retained, they must be paid salaries and given recognition commensurate with their responsibilities and special training.

Indian food inspectors are not adequately paid nor recognised and it also may be true that they are not aware of the importance of the role they play. In the Pune area the total salary package including cost of living adjustments and allowances for entry level food inspectors is approximately 4,500 Rs/month. Drug inspectors get 6,500 Rs/month. Food inspectors, according to their supervisors, are a "hopelessly demotivated" lot because most of them have not been promoted in 20 years. Bribe taking, under these circumstances, is tempting.

The PFA delegates the appointment authority of food inspectors to the states under Section 9 of the act. The powers, and procedures of food inspectors are laid out under Setions 10 and 11 of the PFA Act. The qualifications and duties for food inspectors are laid out in the PFA Rules 8 and 9. Rule 8(c) requires that the food inspector be a graduate in science with chemistry as a subject, or in agriculture or in public health, or in food or dairy technology from a university in India or equivalent; and in addition has received three months satisfactory training in food inspection and sampling work under a food health authority or in an institution approved for that purpose. Despite this requirement, it appears that the liscencing activity is extremely perfunctory and most food inspectors have little knowledge about their responsibilities, although they are graduates in science.

4. Survey of the Central laboratories

I spent approximately two weeks visiting or attempting to visit the central food laboratories in India. These were important to see for two reasons, (1) by all accounts these laboratories were far better staffed and equipped than the state laboratories and limitations in these laboratories were sure to be present at the state and local laboratories as well. (2) These laboratories are by law, the laboratories of last resort, according to the PFA Act. Based on their analytical results, individuals may be set free of adulteration charges or be sent to prison. Their credibility is vital to the effectiveness of the overall food control enforcement process.

The central food laboratories do not provide the degree of consistency to the state analysts that is implied in the PFA in its requirement that the central laboratories work on methods analysis. The central laboratories are also under-staffed and under-equipped (with the exception of Mysore) for their tasks. There is still a great deal of enthusiasm and interest in the work in some of the central laboratories, but the working environment is typically poor: old and inadequate equipment, unrepaired equipment, unpainted buildings, no air conditioning, poor lighting, and limited library facilities. As a result

these laboratories have difficulty getting qualified analysts and have very little credibility with industry and with the courts. This has contributed to a large backlog of food cases in the courts.

Mysore: The central food laboratory at Mysore is in a class by itself. It is extremely well equipped and manned. It would be a credit to any country and it shows what can be done if good people have the will and vision and are given the opportunity to run a first class laboratory. The laboratory is clean, well maintained, spacious and very well equipped with the latest sophisticated instrumentation. There are approximately 700 people on the site and 250 PhDs. They are closely associated with the university and publish about a 100 scientific papers each year.

Unfortunately for the food-control system only about 27 of these people are devoted to the responsibilities under the PFA Act. Although I was told that the assignments always require many more man hours from the other local personnel than this. It is clear that the major function of the laboratory is R&D for the food industry, and it is simply the good fortune of the central Food Laboratory to be located on the same campus and under the same management as the Mysore research facility.

Pune: The central laboratory in Pune is housed in the same building as the state laboratory. This fact is interesting since it bears witness to some industry assertions that the results of the state laboratories and central laboratories may not always be independent as assumed by law. The building is old, circa 1916, and has that "beaten-down" look. Both the main office building of the state FDA Commissioner (Dr Patil) and the central food laboratory building were very poorly maintained and would not be tolerated in the private sector.

There are 150 people of whom 60 are technical, most of these have bachelor's degrees. I believe there were only 2 or 3 PhDs on the staff out of the 150 total personnel. (This can be contrasted with the 250 PhDs who work at Mysore.) The equipment in the laboratories was a mixture of a few modern pieces from World Bank funding and very old wet chemistry apparatus. They had a reasonably modern atomic absorption spectrophotometer and a computer outfitted GLC. They do not have a GCMS (Gas Chromatograph mass spectrometer) and could not really verify pesticide analysis to the degree now typical in the US or Europe. I would estimate that in Pune there is less than 1/20 th of the equipment of the laboratory at Mysore. The benches were at least 30 years old. The building badly needed painting, the lighting was poor, the working conditions were primitive and depressing, and only some of the instruments were in air-conditioned rooms. In addition the laboratories were very crowded and even the laboratory directors complained of a lack of space. The microbiological facilities are simple and classical, there is no capacity for serotyping, phage-typing or DNA probe work.

Despite these limitations, the people seemed remarkably enthusiastic and interested in their work. This was true of the senior people that I talked to, who gladly

explained their work to me. They showed me some research they had done on the food-handling practices of street vendors, on pesticide levels in foods, on the faecal coliform infection rate in water samples and on cholera outbreaks.

The Pune laboratory, as a state laboratory, analyses approximately 1,300 samples per month compared to the 2,300 samples per month handled by the other 29 far smaller laboratories in the Marharashtra district. On average, about 10% or less of the samples are found adulterated. As a central laboratory it analyses approximately 50-100 appellate samples from around the state per month. Confirmation is approximately 50%.

It is really a pity that these people at Pune are not supported better by their government. I think that the Pune laboratory is capable of doing routine chemical analysis and simple microbiological work. but it is not any where near the level in the US or Europe or that exists in India in private laboratories. There could not have been a greater contrast between the working conditions and capability at Pune and that at Mysore.

Ghaziabad: I tried to visit the laboratories near Delhi, but at the last hour the appointment was cancelled. Before I came to India I had stopped off at Rome to talk to the people at FAO who had visited these laboratories. They were very critical of poor equipment, much of it not in working condition. FAO was of the opinion the laboratories were not capable of sophisticated chemical or microbiological analysis.

Calcutta: I was not able to visit Calcutta due to lack of funds. From what I have heard this laboratory is about on a par with that in Pune.

Summary - The central food laboratories as a whole are poorly housed, poorly equipped and weakly staffed by western standards. (The Mysore central food laboratory is the exception, it is very well staffed and equipped.) But despite these limitations the laboratories do a fair amount of work with the facilities they have. There appear to be fours classes of laboratory facilities. The four central laboratories, state laboratories, regional laboratories and district laboratories. The laboratories get smaller and less well endowed as one goes down the list. In Pune for example, the central laboratory (also the state laboratory) is approximately 150 people, the two regional laboratories about a fourth of that and some of the 27 district laboratories consist only of a few people each.

Not all the testing imposed by the PFA Act necessarily demands elaborate or sophisticated equipment. However, the availablity of adequate chemical reagents and standards is vital. Many samples can be analyzed with wet chemistry methods, with simple instuments and a reasonable amount of knowledge, skill and experience. For example, the PFA Act typically requires the analysis of components of foods only down to the 0.01% range or 100 ppm. A small laboratory can typically obtain the means to do extractions, identify substances, measure ash content, fibre, and solids, conduct simple fermentation tests, measure insolubles after acid hydrolysis, iodine number, saponification values, refractive indicies, flashpoint, acid values and do simple microbial

assays. The reports of adulteration from the laboratories of the Maharashtra state and Muncipal laboratories for 1996 give some idea of the capabilities as well as the findings of the laboratories:

> Extraneous colors and foreign starch in tumeric powder, high uric acid levels in wheat, extraneous mineral oil in pepper, non permitted color in Badishep, excessive SO_2 in jam, extraneous castor oil in other oils, iunsifficient volitile oil in cloves, extraneous color in rice, marsala, confectionaries, marsal toast, saccharin in Sarbat lemon, algal groth in ice canday, microbial contamination in mawa, chloral hydrate in toddy, cotton seed oil in Ghee, insufficient iodine content in iodised salt, Lakh dal in Watana dal, Pluses, Toordal and Masoor dal, tumeric/salt in Badi saunf, pea and Jawar starch in Chana bean, aflatoxin in Ground nut cake, extraneous colors in Sweet meat, iron filings in tea powder, excess inorganic matter in tumeric powder, extraneous synthetic color Tartrazine in Mug Dal/Tur dal, trypsin inhibitor activity in trophox, improper fructose to glucose ratio in pure honey.

The average percent adulteration (samples found adulterated/total samples analyzed) from the Maharashtra area was 6.96% in 1996.

These findings suggest quite a degree of skill in the Pune area laboratories. It is not clear from what I observed whether any particular sample in any particular instance in all the laboratories can be analysed in an accurate and timely manner. It would depend on the kind of analysis required, the difficulty of the analysis and the instrumentation needed to get accurate results. What appears to be missing is some formal assessment of quality control, check samples for example, or round robin validations of the individual laboratories. Another issue is the focus of the laboratories which is determined by the samples they receive to analyze and the specifications in the PFA rules they work against. Are the samples selected to best represent the potential hazards in the maketplace?

The laboratories are no match for the laboratories in large companies whose results they may be contending with in the courts. The education, training, sophistication and motivation of these far better equipped industry analysts far exceeds the government analysts. The government laboratories also do not approach the capabilities of developed countries (Mysore again being excepted.)

5. State and Municipal laboratories.

The majority of the municipal laboratories are small, under-staffed and under-equipped, and able to perform only the more routine analyses. Microbiological contamination of food rarely is reported, despite the fact that studies carried out by the central laboratory at Pune and Calcutta with the support of FAO have indicated considerable microbiological health hazards from street food. Some of the state

governments appear not to have not even formulated the state PFA Rules, required under the act.

A problem in the country at large is that most samples never make it to the central food laboratories. In Pune for example, of the 15,421 food samples examined in the state Public Health Laboratory only 303 samples were appellate samples from various courts. so barely 2% of the samples are examined by the central food Laboratory. If this percentage can be extrapolated throughout the nation, only approximately 2% of the annual 50,000 samples are reexamined at the central food laboratories. Most public analysts work at the state or municipal laboratories. These are much smaller laboratories and much less well equipped than the state laboratories. (Pune is an exception because the state food laboratory and the central food laboratory are in essence on and the same.)

6. <u>The central PFA division and the CCFS.</u>

Some of the industry criticisms stem from the highly conglomerate nature of the administration of the food laws. There are several laws, several ministries with different points of view, several sets of rules and many important committees with responsibility in some areas of food control. The functioning of the system is perhaps made even worse in that the principal ministry or ministerial division responsible for the PFA is hobbled by an organisational structure laid out in the PFA Act. The 55-man Central Committee on Food Standards (CCFS) is a major source of the lack of responsiveness at the central level. One cannot operate a food-control system the size and complexity of India's with a committee that meets once a year.

The operation of the CCFS and the staff assigned by the central government is unequal to its task, both in its organisation and in its resources. The ministerial control and co-ordination of the whole is cumbersome, inadequate, and outdated. Perhaps in an earlier time, when India coveted its self-sufficiency, a system that was slow, unresponsive, highly decentralised, uncommunicative and even slightly mysterious served a need. But with the change in national policy, the removal of economic barriers from agro-based industry, and efforts to open world markets to India's products; a stronger, more rapidly responding central food authority, capable of unifying food standards and food analysis in the states is necessary. The very understaffed central unit and unwieldy CCFS committee are embarrassingly inadequate today. An effective regulatory administration capable of timely decisions, adequate means to assure the quality and safety of the food supply and the capacity to deal with international food issues and standards is vital in today's world.

There is inadequate authority at the central level.. A national (or central) food agency is required, There is a need for stronger management and co-ordination between states and the central government, more reliable testing and monitoring capacity for food-borne chemicals and food-borne diseases. Uniform technical manuals, including: an inspectors manual, procedures for sampling, laboratory procedures and analytical

methods need to be developed and made available to the central laboratories. There needs to be a shift in emphasis towards more interaction with industry and consumers and greater accountability and responsiveness at all levels. Only a National Food Agency (NFA) with an adequate manpower and organisation can provide the needed management strength. There is also a need to take the problem of food-borne disease more seriously. An NFA can provide greater visibility and attention to this area. There may be no need for hiring new staff, additional staff may well be found in sister agencies; all the ministerial responsibilities in the food area should be brought under the single NFA.

Among the responsibilities of the NFA should be to: (1) provide national leadership, visibility and accountability for the safety and adequacy of the countries food supply; (2) provide the central planning , management and evaluation for all national inspection, enforcement, surveillance, and monitoring programs; (3) provide the central planning and audits and evaluation for the operations and programs of the central Laboratories; (4) develop regulations, technical documents, surveys and reports etc. as necessary for the implementation of the PFA Act; (5) provide for international liaison and harmonisation with food control agencies of other nations, WHO, the Codex Alimentarius, FAO and WTO; (6) provide for liaison and communication with other ministries, industry, consumer organisations and the public; (7) establish and/or strengthen wharf and port inspection and laboratory facilities and (8) develop and enforce an ethical code of conduct for all its employees.

Consumer and Industry Input in the Food-Control System. - As indicated above, a 1986 amendment to the PFA authorised the involvement of consumer organisations into the implementation of the food laws. But very little has been done to implement this provision. A special unit in the NFA should be established to provide consumer and industry advisory services. Such a unit could serve as a focal point for consumer education programs. Trustworthy information on food values and nutrition is vital in a country where half of a workers wage must be spent on food.

While the law does provide that the government publish notice of an intended rule in the official Gazette, the GSR, the law is observed, but the spirit or intent of the law is not. Instead of sending the relevant proposed rules to affected companies and requesting comments, only a few copies are printed; they are hard to obtain in some communities; and the government does not respond to requests for copies.

Some members of the food industry also complain of lack of input into the process of food law implementation. The CCFS is charged with making secret decisions "in camera", but perhaps this is merely an effort to explain the long delays. The unit for Consumer and Industry Advisory Services could assure that proposed rules were promptly made available to interested observers. This unit could also see to it that appropriate members of industry, technical experts, and consumers were invited to participate in matters of importance to them and in issues where their advice and

experience would be of value to the government. Advisory panels are widely used in food related matters in all Western countries and provide invaluable assistance.

7. The PFA Act

My detailed analysis of the recommended changes to the PFA Act proposed by the Task Force is provided in Appendix 1. I agree with most of the suggested changes and would add a few others.

Where I disagree, for the most part, are in those areas where the task force attempts to repair what I regard as a deeply a flawed provision, which I would prefer to eliminate entirely. Another general area where I disagree with the task force is in their apparent belief that fixing the PFA Act by itself can lead to fundamental improvements in the safety of the food supply or in the reduction of regulatory barriers. I believe that fundamental improvements are also needed in the bureaucratic infrastructure in the food-control system and unless these are made together with changes in the PFA, very little benefit will come from statutory changes alone.

Municipal and State laboratories

For example the task force recommends fixing Section 13.3 to permit the vendor to obtain a sample for his own analysis. I understand the purpose is to promote greater fairness and honesty in the analysis of samples. However, India is virtually alone in the world in the degree to which it anticipates that its own public analysis of food samples will be flawed and establishes a scheme for the retesting of food samples by other laboratories of the same government. This is a self-defeating scheme, first it sets up two classes of laboratories, the first which is likely to get things wrong, the second which by statute can make no error. It virtually guarantees unnecessary duplication of effort. It encourages a built-in inferiority in the state public laboratories and virtually guarantees that when the funding of laboratories is decided, that the state laboratories will be treated as second class citizens.

My proposal is to gradually eliminate the municipal and state laboratories and increase the number of central laboratories to approximately 10 or 12, which I calculate can do the same job even without improvements in efficiency. There are approximately 78 municipal and state food labs in India; they are poorly equipped and weakly manned. They do not get adequate support from their state governments. The only way I see to assure that the PFA is properly implemented is to place those laboratories under the responsibility of the central government. It is also a practical solution; it is much easier to equip and maintain 12 laboratories than 78 laboratories. It would also mean that the laboratories are larger, all would have a "critical mass" of analysts and all could be made competent to conduct the appropriate tests. It would also provide a means of assuring consistency in the analytical methods and in the quality of the laboratories. An adequate central or national food authority in Delhi that has the responsibility of directing and auditing these laboratories is of course essential.

"Clean Shop" Provision

Another area of statutory reform I would add to the task force's list is in the hygiene area. Section 2(ai)(e) in the PFA states:

"--an article of food shall be deemed to be adulterated:- (e) if the article had been prepared, packed or kept under unsanitary conditions whereby it has become contaminated or injurious to health; "

As written, this provision requires that adulteration be found before a charge can be made. In other words it is not illegal in India to run a dirty or unsanitary food facility. per se. This statute can be compared with several others around the world.

In the US, The FD&C Act Section 402(a)(4) states: *" A food shall be deemed to be adulterated- if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.*

In Sri Lanka, The Food Act of 1980, Section 2(2) states: *" No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions."*

Section 2(3) states: *" No person shall import, sell, or distribute any food manufactured, prepared, preserved, packaged or stored for sale under unsanitary conditions."*

In Kenya, The Food, Drugs and Chemical Substances Act of 1992 (Revised from 1980) Part IIA, Section 7, states: "*Any person who sells, prepares, packages, conveys, stores or displays for sale any food under insanitary conditions shall be guilty of an offence*."

India is virtually the only country, where modern food laws exist, where it is permitted under the food laws to prepare and store food in an unsanitary shop.

If only one recommendation is adopted from this report, this should be the one: Make it illegal to run an unsanitary food facility. The simplest way to do this would be to put the words "may have become contaminated" back into Section (2)(e) where they apparently were extracted originally. This provision appears to be a direct copy of the comparable US provision, with the key words omitted.

This "clean shop" statutory provision has become very important world wide, because it provides the legal underpinning for HACCP (Hazard Analysis and Critical Control Points) the procedure that has been adopted in most western countries wherein the food industry itself undertakes responsibility to assure and control the safety of its food products during all stages after primary production, during preparation, processing,

manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer.

A recent EC Directive (ECC,1993) mandates HACCP for all Member states. The Directive gives 30 months (not later than 31 December, 1998) for Member states to bring into force the laws, regulations and administrative provisions necessary for compliance. If a hygiene problem likely to pose a serious risk to human health arises or spreads in the territory of a third country, the EC Commission, either on its own initiative or at the request of a member state, may suspend imports from all or part of that third country. The Directive is accompanied with an annex which lists the rules of hygiene that shall be complied with. The Codex Committee on food hygiene has recently revised its main document "Recommended International Code of Practice; General Principals of Food Hygiene" to incorporate risk assessment principles and to include specific references to the HACCP system. (Whitehead, 1996).

Under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), each member nation of the WTO, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of protection as is provided by menbers of its own system. Equivalent regulatory systems need not be identical. The SPS measures include al the relevant laws, regulations, procedures, production measures, testing and inspection procedures that bear on the protection of human health from risks in food. Under the concept of equivalence, the sanitary and phytosanitary measures used by an exporting country may differ from the measures applied domestically by an importing country so long as these measures " achieve the importing Member's appropriate level of sanitary or phytosanitary protection. Under the SPS agreement, the burden of demonstrating that equivalence exists rests with the exporting country. India's existing PSP measures would not meet the standard of equivalence of western countries in most cases. The US has recently published Draft Guidance on Equivalence for Food,, Fed Reg., June 4, 1997, Number 107

One of the major suggestions offered in this report is aimed at improving the sanitation controls on food, particularly at the local, food-handling level. Instead of conducting analyses of food, which should be transfered to the central laboratories (suitably strenghtened and improved); the local, municipal and state officials should emphasise instruction in sanitary practices for the small-scale, unorganised food-sectors. India is way behind western countries in the importance it attaches to food sanitation. The emphasis of chemical contamination and standard deviations is misplaced given the relative neglect of sanitation issues. Upgrading instruction in sanitation at the local level, upgrading GMPs and HACCP in medium and small-scale food processing operations and upgrading the central Laboratory Facilities in the microbiological area should be major priorities.

IV. Summary of Recommendations

A Major Conclusion

Changing the law will help discourage corruption. But changing the law without improving the reliability and capacity of the laboratories will just increase the backup in the courts and create more frustration with inadequate food-sample analyses. Improving the efficiency of the bureaucracy and the capabilities of the laboratories without changing the law will just exacerbate the unfairness of the system and encourage more corruption. And doing both without extending the scope of the food-control system to the local communities in the form of instruction, and education on food safety and monitoring for proper food hygiene in small food establishments, will leave out the greater portion of the Indian population.

The major problems with the current Indian food-control system can be separated into those with the PFA Act itself and those with the organisation and management of the food-control system: Inspection system, state laboratories, central laboratories, and central staffing and management. The recommendations for improvement in these areas are listed below

A. Recommendations on the PFA Act

(1) The current act has unjustifiably harsh, undiscriminating and self-defeating penalties for violations of the adulteration provisions. Severe penalties should be retained for harmful fraud or intentional adulteration but magistrates ought to be given discretion to impose appropriate fines and/or lessor prison sentences for unintentional, unharmful and technical violations. In addition, the appropriateness of the penalty to the size of the business of the person charged as well as the gravity of the violation should be considered.

(2) The current act has only weak authority over food sanitation and food hygiene. Preparing or processing food in an unsanitary facility is not a violation of the adulteration provisions of the current PFA Act. It should be, and Section 2 (ia)(e) should be modified to make it so. The preparation or storage of food in unsanitary facilities *per se* should be and are violations of the food laws in most countries of the world. There also should be provisions in the PFA Act that mandate compliance with GMPs and HACCP and corresponding instructions in the Rules.

(3) The current act, in essence, establishes a committee, the CCFS, as the central food Authority for India (PFA Act, Section 3). It is impossible to adequately manage a food-control system the size of India's with a committee that meets only a couple of times a year. A permanent, and well-staffed national agency with a single responsible individual at its head in needed. The CCFS should be abolished and a National Food Agency established in its stead.

(4) The current act (Section 13) envisages re-examination of state regulatory samples by the central laboratories upon request of the defendant. Given the poor state of analytical capability in the local laboratories, it is understandable why this provision is so desired by industry. However, this statutorily imposed system of central Laboratory verification is wasteful, corrupting and ultimately self-defeating. Under the reform proposals offered, only the central laboratories will conduct regulatory analyses and write corresponding analytical reports. Of course, this proposal is contingent on the development of adequate central laboratories. Accordingly the provisions (Sec. 13(2) and Sec. 13(3) will not be necessary and should be eliminated from the act. The analytical reports of the central laboratories will be considered final evidence of the facts stated therein.

(5) The entire PFA is cumbersome and largely out of date. In addition to the specific changes recommended, some consideration should be given to the redrafting and simplification of the entire law. There is an unnecessarily complex section on adulteration, details on sample analysis that are best left to regulations (or Rules)

(6) Some thought should be given to rationalising PFO requirements with PFA requirements. There is a lack of consistency in several areas, fruit products, condiments, vegetable products, pickles and synthetic beverages to name a few. (See Appendix A) The PFO inspection of food plants is similar but less effective than GMPs in the US There is good reason to place these under the PFA. This would eliminate the need for inspection by two different governmental authorities.

(7) There is no mention in the current act of the recent international Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) agreements to which India is a signatory. There should be a provision in the act which acknowledges these agreements and indicates the responsible authorities and method(s) of compliance.

B. Recommendations on the Organisation of the Food Control System.

(1) There is inadequate national food authority. As indicated above (3), a national (or central) food agency is required, There is a need for stronger management and co-ordination between states and the central government, more reliable testing and monitoring capacity for food-borne chemicals and food-borne diseases, a shift in emphasis towards more interaction with industry and consumers and greater accountability and responsiveness at all levels. Only a National Food Agency (NFA) with an adequate manpower and organisation can provide the needed management strength. There is also a need to take the problem of food-borne disease more seriously. An NFA can provide greater visibility and attention to this area.

(2) Among the responsibilities of the NFA should be to: (1) provide national leadership, visibility and accountability for the safety and adequacy of the countries food supply; (2) provide the central planning and management for all national inspection, enforcement, surveillance, and monitoring programs; (3) provide the central planning and audits for

the operations and programs of the central laboratories; (4) develop regulations, technical documents, surveys and reports etc. as necessary for the implementation of the PFA Act; (5) provide for international liaison and harmonisation with food control Agencies of other nations, WHO, the Codex Alimentarius, FAO and WTO; (6) provide for liaison and communication with other ministries, industry, consumer organisations and the public; and (7) develop and enforce an ethical code of conduct for all its employees.

(3) There are several ministries with authority over various aspects of the food area: weights and measures, essential commodities, food processing, food production and others. These responsibilities should all be examined in light of the proposed new National Food Agency and relevant responsibilities shifted to it.. Currently a multiplicity of regulations governing food are administered by various ministries with varying regulatory viewpoints. There is overlap of authority, duplication of functions lack of co-ordination and much confusion. One of the anticipated results of the proposed reorganisation is better management and co-ordination of these efforts.

(4) The responsibilities of the 78 state laboratories need to be redefined. It is proposed that their current responsibilities for regulatory sample testing be shifted to the central laboratories and the number of these latter be increased from 4 to approximately 12. The Current state and municipal laboratories should be converted to district offices with new responsibilities to include: (a) regulatory sample collection and case preparation; (b) food code and HACCP inspection of local food manufacturers; (c) consumer and local food producer education (d) disseminating of sanitary food handling and food safety information.

(5) The existing and the new central laboratories need to be adequately staffed and equipped to analyse any required food sample in a timely manner with documentable reliability and credibility. This includes both chemical and microbiological samples. Some of these laboratories may specialise in various types of food analyses as deemed appropriate by the central food Agency.

<u>Alternative to the proposal to establish new central laboratories.</u>

Some critics of the present system have objected to the inadequacies of the current laboratories and have proposed to privatise the system. They would establish privately run, government certified laboratories instead of government run laboratories. This, on first inspection, is a viable alternative, privatisation is much in vogue lately and it promises satisfactory results and better responsiveness at possibly less cost to the government.

I don't recommend it because it seems to me that the work of the laboratories is vital to the integrity of the enforcement of the PFA. A government cannot abdicate its responsibility in an area as important as the safety of the nation's food supply, simply because it is doing a poor job today. I think handing over this large a responsibility to

the private sector is something the government should think over very carefully, should it be so inclined.

The recommendations in this report are the personal views of author not those of Indian food officials nor members of Indian food industry. It is not expected that the author's opinions and recommendations will be wholly shared by these individuals. But a shared vision of the future needs to be developed by the concerned parties in order to have a reasonable chance for improving the current food control system and making the necessary changes.

Both the current bureaucracy and the industry have strong opinions on the major issues and these are mutually well understood. Several seminars, workshops and meetings on these issues have be held over the past few years and further meetings, while not necessarily futile, do not appear to hold much chance of accomplishing very much. Accordingly, I propose that a new approach be tried which involves neither party in a primary role.

I suggest that a high level panel be commissioned, composed of independent, well regarded individuals of some eminence in both government, industrial and international circles. This panel should be commissioned at the highest level and charged with the job of making recommendations to the parliament on the changes needed to improve the food control system. The charge to the panel should include all aspects of the food control system not just proposed statutory changes. Members of the current food bureaucracy, members of the food industry, and members of WHO, FAO and other international organizations could be invited to testify before the panel as required. I suspect that the panel would retrace in a more comprehensive way the path that the author has taken in this report. Perhaps many of the suggested changes would be the same, but this time the recommendations would represent an Indian vision and stand a better chance of finding a broad base of support in the parliament.

APPENDIX 1

(4) Comments on the Statutory Amendments

4.1 Title .... page 20 no comment

4.2 Definitions .... page 20

The "Report" does not take any issue with definition 2(ia)(e) which declares an article adulterated : "if it had been prepared, packed, or kept under unsanitary conditions whereby it has become contaminated or injurious to health" This provision has clearly been patterned after the US FD&C Act, but with an important omission. The comparable provision in the FD&C Act, Section 402 (a)(4), states that a food shall be deemed to be adulterated:

" if it has been prepared, packed, or held under unsanitary conditions whereby **it may have been contaminated** with filth or whereby in may have been rendered injurious to health."

(4) The phrase "**may have become contaminated"** is vital to give important force to this provision. The language of the US provision, in effect, requires food processors to run a sanitary food facility and makes it a violation of the law not to do so. If a US food inspector finds an unsanitary facility, whether or not there is detectable adulteration of food, he may make a charge of adulteration under 402(a)(4). He is not obliged to ignore an unhealthy condition, where common sanitary practices are violated and adulteration is inevitable simply because the food has already been shipped or actual food adulteration at the time of inspection is not evident. This is the statutory provision that stands behind US GMPs and HACCP. India is perhaps the only country in the world which legally permits a person to run a dirty food facility. The way the PFA is drafted definition 2(ia)(e) is redundant, for the corresponding actual adulteration is covered under definitions 2(ia)(f) and 2(ia)(i).

The "Report" states that a major purpose of the reform is: "to bring the law in harmony with the needs of the present day society" (page 8), or in a similar vein, " to shift the emphasis away from the detection of adulteration and prosecution to the promotion of "good manufacturing practices"(page 1). By leaving definition 2 (ia)(e) as it is in the PFA , the Task Force misses a very large opportunity to achieve these stated goals.

4.3 Section 2(i) .... page 20

There is a very interesting difference between the PFA Act and Western food statutes concerning "adulteration". The focus of the US FD&C Act for example, is on adulteration as an act of food debasement, not on adulterants *per se*. The adulteration of food with anything is the illegal act, and one may even say that it is the 'adulterated

food' that is regulated not 'food' itself and not the adulterant. An adulterant is not even defined as such in the FD&C Act or in other Western Food Statutes.

(5) You might consider focusing on adulteration of food rather than on the use of adulterants. It may be undesirable or too ingrained in Indian law for you to consider such a fundamental change, but there would be certain advantages if you did. Section 2(i) defines an adulterant in an entirely open ended manner; under the given definition, virtually any substance could be an adulterant. As such, the definition is mischievous. Under the PFA Act, the finding of a any chemical in a food processing plant is or could be in violation of the act. It's up to the producer to show that it is not. Since any chemical, could at some concentration, be a food adulterant, this provision would seem capable of causing endless mischief and capricious litigation.

4.4 Section 2(I) Proposed Amendment.....page 21

I agree with the spirit of the suggested change, but for the reasons indicated above, I would suggest you consider a more fundamental change in the PFA. Even with the proposed amendment, there is the possibility for litigation over what constitutes "reasonable ground". This issue seems to be the result of an awkward drafting in the first place, and a fundamental change could help in the other amended areas as well.

4.5 Section 10 (7b) .....page 22 No comment

4.5 Section 11(5)(b) and 11(6)(b).....page 22 No comment

4.8 Section 2(**ia**) ..... page 23

Provision 2(**ia**) (a) is an interesting provision and it would appear on its face to be unenforceable, mischievous and quite unnecessary. The problematic phrase is "demanded by the purchaser". This provision would appear to require very little objective evidence to be triggered. For example, only the purchaser's statement of what he demanded, would appear necessary. This provision also seems to give the purchaser virtually unlimited power over the vendor.

This language apparently comes from the English law. Such a provision does not appear in the US FD&C Act but is does in others. A similar provision was retained in the 1990 up-date of the UK Food Safety Act. It essentially establishes an implied warranty that the food is what the consumer had a right to expect. The British probably rely heavily on centuries of case law to define the provision and render it workable. It would be interesting to find out what added authority this provision gives to the PFA Act in a practical way. It would appear to be redundant if the adulteration provisions are adequate. It would also seem to be implicitly covered by the presence of standards of identity in the rules. A standard of identity for a food is the way the consumer is assured of receiving what he has a right to expect.

(6) If one were starting over from scratch, I would suggest that consideration be given to eliminating this language, while retaining the other language in the provision. But, again, if the case law is adequate in defining what it means under various conditions, and the provisions are in keeping with cultural expectations, perhaps such a provision is workable. .

4.9 Section 2(**v**) .....page 23

I agree with the amendment. Drinking water for human ingestion should be covered by the act; it is most important to do so. Contaminated drinking water is perhaps on of the major health problems in India, and the source of tens of thousands of deaths particularly by diarrhoea in children. If greater attention can be given to this problem by making potable water a part of the PFA Act, it would be well worth the effort.

(7) As a matter of logic and greater clarity I would recommend that the definition of food be placed earlier or possibly first in the definition section. The term "food" is used in the act Section 2(ia) before it is defined in Section 2(v) several paragraphs later on.

4.10 Section 2(xiii).....page 24 No comment

5.2 Section 7 .....page 26 No comment

6.2 through 6.8 Section 3.....page 27

Several amendments are offered to change the organization and representation to the central CCFS. As I have indicated in the body of this document, I believe these proposals are inadequate. A committee of 55 people that meets at most once a year cannot manage the food-control system of nation. Major countries have an independent department or agency responsible for the implementation of the food laws, not a committee. A central committee lacks the decisiveness and quickness needed to resolve contemporary food safety problems and also lacks the focus and political weight needed to get funding and public attention. It also cannot provide adequate management. A permanent, central staff is needed to provide leadership in food safety, to manage the central laboratories, write regulations and standards, undertake the harmonization of standards and methods required under SPS and the WTO agreements.

6.9 Section 8.....page 32 No comment

6.10 Section 8.....page 33 No comment

6.11 Section 8A..... page 34

It is probably not a good idea to attempt to prescribe science by statute. It is better to place such requirements in the rules, which can be modified more easily.

However, if such a prescription were offered inder the current system many laboratories would not be able to comply because all the laboratories are not sufficiently well equipped. In any event, I don't think this particular provision is sound. What is desired in an analytical method is accuracy, precision and reliability. If these qualities are present in different methods they can all give reliable results.. By prescribing a common method in the statute, you may well be inhibiting the development of new, faster and more reliable methods and retarding innovation. What is needed is a system of central laboratories that are well staffed, well equipped and well managed under a National Food Agency. This would allow the NFA to assure that the methods used in each laboratory were reliable and as uniform as considered necessary.

7.3 Section 10 (1)(c).....page 37 No comment

7.4 Section 10(2) .....page 37 No comment

7.5 Section 10(9).....page 38

The proposed amendment to PFA Section 10(9) recommends increasing the punishment to food inspectors for committing "vexatious acts". Unlike the trend established by proposed amendments in other sections to decrease penalties for violations of the act, this amendment would increase them. The Draft text does not really describe why the current provision is regarded as inadequate but it is apparent to anyone who understands the system that these fines are intended to reduce the taking of bribes by inspectors. The argument given to adopt the analogous section in the Indian Penal Code, Section 166, is not compelling. The Penal provision requires 'knowing disobedience of the law and 'intent to cause harm". The PFA provision, 10(9), is weaker and covers a wider variety of lessor acts.

(8) It appears that this section of the act should indeed be modified and the current penalties strengthened as is proposed, but more consideration should be given to making the "punishment fit the crime". Some "vexatious acts" are willful and intentional and should be harshly dealt with, others can arise out of carelessness, a lack of proper oversight, or even a lack of resources. As indicated in the body of the document, I would propose abolishing all local and state laboratories and give their function to newly created central laboratories. This would break the link between local inspectors and local analysts which contributes to the present situation.

7.6 Section 10 ....page 39 No comment

7.7 through 7.13 Section 11 .....page 41-43

The objective of this proposed amendment is desirable and sound; however, I think the provision could be improved. The objective sought in making the sample available to the defendant it to assure that the analysis of the sample will be actually carried out and done correctly by the state. The fact that the sample is known to be

available to the defendant for his own analysis helps assure that the state's inspectors will not willfully and dishonestly claim the that the sample is violative when it is not. The sanct[illegible] in the provision, is in the threat that the defendant is legally and technically capable of doing so. In order to insure this threat is real, the defendant must be able to obtain the report of the state's analyst in a reasonable time prior to his trial. This his an essential part of the quoted US statutory provision, section 304(c), [not (a)(3)(B)(c) as given in the "Report".] The state's analyst's report is the essential factual information on which the outcome of trial will hinge. The defendant and his attorney need a reasonable time to study the analyst's report to see that the samples were properly analyzed and the data was properly interpreted. Then the defendant may decide to carry out his own analysis. Clearly the rules must specify the content of the analyst's report so that it is written in sufficient detail to permit an adequate appraisal of the results.

(9) Include a provision in the proposed statutory changes that the defendant be provided with a representative sample of the article and the analyst's report in a reasonable time prior to trial. Write suitable conforming amendments to the rules governing the completeness, transparency and accuracy of the analyst's report.

7.14 Section 13 (2E).....page 43

Sections 11, 12 and 13 of the PFA Act are unusual from the point of view of a U.S. observer. Essentially most of the material covered in these sections would be written into Regulations (Rules) by the FDA or into Compliance Guides, written by the enforcement sections of the FDA. They would not be a part of the statute itself. However, this presumes the existence of a national food agency responsible for both regulations and enforcement. This is not the case in India, and I won't presume to suggest such a radical change without a better understanding of the operation of the food laws in India. I would inform you , however that precisely such a change will be offered in the UK as an outcome of the BSE incident. There are very significant advantages to such a system. For example, at the FDA, one can change the Regulations and Compliance Guides without requiring a statutory change. This gives the FDA the ability to incorporate new administrative procedures and repair badly working procedures far more easily and quickly than getting the basic statute changed.

(10) I suggest you consider the formation of an independent food agency. Unless such a proposal is totally impossible given the reality of Indian politics, it has a lot to recommend it. This act, by itself, would establish food safety as an important governmental priority, would help meet the objective of modernizing the food safety administration, would focus public attention on the problem of food safety, and would reduce the amount of statutory micro-management of the administration of the act and minimize obscuring the act with unnecessary detail.

8.1 Section 14 .....page 48 No comment

9.1 Sections 16 - 21 .....page 49

Pages 49 through 70 of the report are concerned with sections of the statute relating to punishment for violations of the act. In general the "Report" takes the position that, many of the current provisions inflict irrationally harsh penalties. From my reading of the PFA Act, I would agree; it also seems to me the focus and dependence on punishment is overdone both in the law and in the attention given to it in the "Report". Such changes, while desirable on other grounds, are unlikely to have a great impact on the safety of the food supply. They deserve attention, but is this the place?

In the U.S. and the UK, the major punishment for violations of the food laws is not even in the statute. It is the sharp, unfavorable glare of media attention that important violations of the law receive that is the real punishment. In the US, typically the violation occurs in connection with a consumer complaint, an illness produced by a contaminated food. This incident is traced by FDA or by CDC (Centers for Disease Control) to a specific food product. A single incident of botulism from a canned food or *E Coli* 0157 in a processed meat product, or from *Salmonella* in eggs or in chicken, is quickly announced by the press, TV, radio and other media as the FDA puts the word out to warn the public. The firm "voluntarily" recalls the product, although the firm is under enormous public pressure to do so, so the term "voluntary" is something of a misnomer. The loss of a business reputation, or few days loss of trade or, more, in some cases, costs the offending firm thousands or sometimes millions of dollars. Unfavorable publicity of the recall, in serious cases, can essentially destroy the firm, as people boycott the product. The reaction of the firm is typically, enthusiastic, if tardy, collaboration with the FDA following the incident, in order to get a clean bill of health so that food sales can resume. Of course there are also fines, and in rare cases, jail sentences for certain violations as well, but these play a minor role in the act's enforcement. The fear of adverse publicity and the loss of reputation during a voluntary recall is the real enforcement tool. Of course actual cases are important and need to be prosecuted to assure that the law is taken seriously. But the bulk of the public education about food safety and the habit of compliance with the law does not occur because of the fines, which are small in proportion to the financial capacity of the businesses involved. .

Another point worth mentioning is the need to gain the cooperation of food manufacturers in preventing the conditions that produce unsafe food. This is better done by a carrot than a stick. No government can protect the public against unsafe food without the cooperation of the food industry. The emphasis, wherever it is possible, should be to get the support of the industry in preventing unsafe conditions and building value into their product by assuring its safety. According to current observations in many countries, the central government's major role should focus more on: communicating to the public, providing the technical know-how to the states, making available the newest scientific information, supporting the system infrastructure, rapidly tracking down food borne disease outbreaks and providing leadership and less on punishing the guilty. As far as food safety is concerned, focusing too much on punishment for violations is just not cost-effective.

APPENDIX 2

Examples of anomalies, internal inconsistencies and absurdities in the PFA and FPO

1. Honey is permitted in Fruit Jelly (A.16.15), but not in Jam (A.16.07) or Marmalade (A.16.09).

2. Saccharin (A.07.10) can be used in specified foods, but Aspartame (A.07.12) is sold only as table top sweetener for use of diabetics, under medical advice.

3. FBO permits artificial colouring matter in canned cherries and strawberries, but not in other fruits, and in canned peas, but not in other vegetables.

4. The use of tartaric acid is specifically prohibited in jam (A.16.07), but permitted in marmalade (A.16.09). Jam is permitted to contain malic acid, but not marmalade or fruit jelly.

5. Malic and tartaric acids can be added to fruit juice (A.16.01), but not to fruit syrup (A.16.03), fruit squash (A.16.04) or fruit drink (A.16.05)

6. According to rule 72, the amount of acetic acid, citric acid, DL-latic acid and malic acid added to foods is limited only by GMPs, whereas for tartaric acid a limit of 600 ppm is set.

7. Rule 55 specifies widely varying levels of SO_2 as a preservative in different dried fruits.

8. Rule 64 B stipulates that monosodium glutamate may be added to food provided the total glutamate content of ready-to-serve food does not exceed 1%.

9. Under FPO, Flavoured Sweetened Aerated Water is permitted to contain phosphoric acid, caffeine and gelatine only if the fruit juice content is less than 10%. On the other hand, the addition of ascorbic acid and latic acid are permitted if the fruit juice content is more than 10%.

10. Rule 72 does not include fumaric acid among the acidulants permitted for use in foods, yet the standards of identity of several fruit products (A.16) include fumaric acid as an ingredient.

11. Rule 72 does not provide for the use of sequestering and buffering agents in hard cheese (A.11.02.07), but the standards of identity under Appendix B permits them. In the case of processed cheese spread (A.11.02.07.02), Rule 72 permits only polyphosphate, whereas the standard of identity includes several.

12. Rule 59, governing the use of antioxidants in foods does not provide for their addition to sugar-boiled confectionery (A.25.01), chewing gum (A.25.02.02), milk powder 9A.11.02.14), and skimmed milk powder (A.11.02.16), but their respective standards of identity under appendix B, permit the addition of antioxidants.

13. Rule 59 permits antioxidants in Ghee (A.11.01.21), but the standard of identity has no such provision. Rule 44 also permits the presence in Ghee of only what is exclusively derived from milk fat.

14. Under Rule 55 chewing gum (A.25.02.01) and bread (A.18.14) are not among the foods in which the use of preservatives is permitted; their standards of identity under Appendix B, however, permit such use.

15. Rule 29 does not provide for addition of color in chewing gum (A.25.02.02) and synthetic syrup (A. 07.08.01), yet their standards of identity under Appendix B permit it.

16. Amaranth (A.25.02.01) and fast red (A.26.13), which are included in Appendix B are not permitted under Rule 28.

17. The standard of identity for malted milk food (A.18.12) does not permit addition of color, but rule 42 provides for label declaration of added color in the product.

18. According to PFO, any beverage that does not contain at least 25% of fruit juice in its composition.... shall be described as a synthetic syrup. The use of the word 'fruit' on the label of such products is prohibited. Yet fruit drink (ready to serve beverages) and fruit nectar, recognised fruit-based beverages under FPO have fruit juice contents of 10% and 20% respectively.

19. PFA provides for a minimum fruit matter content of 5%, whereas FPO standards stipulate a minimum of 10%.

20. PFA permits sorbic acid in addition to benzoic acid and sulphur dioxide as preservatives in fruit products. FPO does nor list sorbic acid as a permitted preservative.

21. The PFA Rules permit the use of emulsifying and stabilising agents in fruit juice but these are nor permitted under FPO.

22. FPO prescribes a minimum of 85% fruit juice in the final product but there is no such specification under PFA.

23. FPO allows the use of permitted colors in tomato juice , but under PFA, the colors are allowed only in canned tomato juice.

24. There is no specification laid down for soyabean sauce under PFA, they are mentioned only in respect to the prohibition of coal- tar colors. FPO prescribes specifications for soyabean sauce and permits the use of coal-tar colors other than the red shade.

25. For fruit syrups, PFA prescribes sugars as essential, while under FPO these are optional ingredients.

26. For fruit chutney, FBO allows the use of permitted colors, but the same is not allowed under PFA. The PFA does not mention the microbiological criteria prescribed under PFO.

27. FPO permits the use of jaggery in sauce, while PFA does not allow it. The use of colors is prohibited under PFA, while PFO permits the use of colors other than red.

28. For tomato puree/paste, FPO limits fungal contamination, and prescribes mold count, while PFA does not mention either.

29. Minimum standards for acidity and soluble solids for spice based sauces are respectively, 1.2% and 15% under PFO and 1.0% and 10% under PFA.

<u>Examples of Need for Updating</u>

1. FPO (PartXX) recognizes only sanitary top cans, bottles and jars ascontainers for various categories of products. Flexible pouches, laminated tubes, aseptic bags, plastic-paper board-aluminium foil cartons (Tetrapack) and thermoplastic containers do not have official sanction for their use.

2. The minimum equipment requirements for a fruit and vegetable processing factory, specified by FPO (Part IB) relate only to process technologies for pulp, juice, squash, jam, pickle and such products. Modern manufacturing facilities involving dehydration, freezing, aseptic packaging or irradiation require correspondingly different minimum requirements.

3. PFA permits aspartame in soft drinks and permits saccharin in soft drinks, but forbids the combination of the two sweeteners in soft drinks or in any article of food. (Rule 47) All the major soft drink manufacturers have found that mixing two sweeteners in soft drinks makes a better beverage, so much so that single sweetener beverages are rarely manufactured.

4. The list of approved colors in the PFA is very short, shorter than approved lists of colors in most western countries. There may be some trouble down the road under the PSP and TBT directives. India is a signatory to these directives and has thereby promised not to impose unjustified restrictions on imports. A list one industry

representative I interviewed was in a position to claim such an unjustified restriction on his imports.

5. The fat content of milk can be low for a number of reasons, e.g., the breed and age of the animal, its state of health, its stage of lactation, its access to water, and its nutritional status. When the fat content of milk falls below its standard value, it is not necessarily true that it has been diluted with water. Better methods of analysis than those used at some government laboratories (Horvet vs. Gerber) can identify and quantify extraneous water in milk and avoid unfair charges of adulteration.

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List of Contacts

No.	First Name	Last Name	Organization Name	Address	State
1	K.P	SARIN	ALL INDIA FOOD PRESERVERS ASSOCIATION	Aurobindo Place, Aurobindo Marg, Hauz Khas	New Delhi
2	SHASHI	SAREEN	APEDA	3rd Floor, Ansal Chambers No.2,6,Bhikaji Cama Place	New Delhi-110 066
3	R.N	SHARMA	BUREAU OF INDIAN STANDARDS	Manak Bhavan,9 Bahadur Shah Zafar Marg	New Delhi-110 002
4	HARDEEP	SINGH	CARGILL	P.O.Box: 3909	New Delhi-110 049
5	R.	PRAKASH	CENTRE FOR PROCESSED FOODS	P.B.NO. 8058,Sadashivnagar, P.O	Bangalore-560 080
6	DR. A.S	AIYAR	CENTRE FOR PROCESSED FOODS	CSIC complex, P.Box.1209, Indian Institute of Science	Bangalore-560 012
7	PRADEEP H.	CHORDIA	CHORDIA FOOD PRODUCTS LTD.	Plot No. 48/A,Parvati Industrial Estate, Pune Satara Road	Pune-411 009
8	VIJAY	SARDANA	CIFTI	Federation House, Tansen Marg	New Delhi-110 001
9	S.P	PILLAI	CIFTRI	Central Food Technological Research Institute	Mysore-570 013
10	D.S	CHADHA	CONSULTING FOOD SCIENTIST	B-1/25,Ashok Vihar, Phase-2	Delhi-110 052
11	PROF. P.A	SHANKAR	DAIRY SCIENCE COLLEGE	University of Agricultural Sciences, Hebbal	Bangalore-560 024
12	LISA	KITINOJA	EXTENSION SYSTEMS INTERNATIONAL	73 Antelope Street, Woodland	California-956 95
13	SUMIT	SARAN	FICCI	Federation House, Tansen Marg	New Delhi-110 001
14	REKHA	SINHA	ILSI-INDIA	6, Commercial Complex, Mayfair Garden	New Delhi-110 016
15	D.H.PAI	PANANDIKER	ILSI-INDIA	905,Ansal Bhawan,16.K.G.Marg	New Delhi-110 001
16	R.K	MALIK	ILSI-INDIA	905,Ansal Bhawan,16.K.G.Marg	New Delhi-110 001
17	G.D	CHOWDHURY	INDIA ICE CREAM MAKERS ASSOCIATION	29,Hanuman Place	New Delhi
18	G.D	HIREBET	IQF FOODS LIMITED	134/1,4th main Defence Colony,Indiranagar	Bangalore-560 038
19	N.M	KEJRIWAL	KEJRIWAL ENTERPRISES	312, World Trade Centre, Barakhamba Lane	New Delhi
20	LAURENT	MATHIS	MARIE BRAZARD	4 F Hansalya, 15 Barakhamba Road	New Delhi
21	RAGVINDER S.	REKHI	MC DONALD's INDIA PRIVATE LIMITED	10, Basant Lok Community Centre, Vasant Vihar	New Delhi-110 057
22	DR.BINOD K	MAITIN	MC DOWELL & CO. LTD.	Shariff Chambers (2nd Floor), 14, Cunningham Road	Bangalore-560 052
23	M.L	MADAN	MINISTRY OF AGRICULTURE	Krishi Bhawan	New Delhi
24	DEVDAS	CHHOTRAY	MINISTRY OF FOOD PROCESSING INDUSTRIES	Panchsheel Bhawan, Khel Gaon Marg	New Delhi-110 049
25	S.R.	SALUNKE	MITCON	P.B. No. 923, Kubera Chambers, Shivajinagar	Pune-411 005
26	J.S	SRIVASTAVA	MODERN FOOD INDUSTRIES (INDIA) LIMITED	Palika Bhawan, R.K.Puram	New Delhi-110 066
27	P.N.	REDDY	MOTHER DAIRY	Patparganj	Delhi-110 092
28	R.K	GUPTA	MOTHER DAIRY	Patparganj	Delhi-110 092
29	P.P.S	DHILLON	NESTLE	DLF Centre, Sansad Marg	New Delhi-110 001
30	S.K	VERMA	NIRULA'S CORNER HOUSE LIMITED	C-69, Okhla Industrial Area , Phase-1	New Delhi-110 020
31	PURVEZ	BILIMORIA	PEPSI FOODS LIMITED	NA	NA
32	DR. J.R.	VAKIL	RWK	Geet Govind 796,Bhandarkar Institute	Poona-411 004
33	DR.N.K	PANDEY	STERLING HORTICULTURE & RESEARCH LTD	#174,Aicobo Nagar,II Stage	Bangalore-560 038
34	SRIDHAR K.	BHAT	TEDMAG	657,5th Cross, 3rd Block, Koramangala	Bangalore-560 034

Agribusiness Information Centre

(FICCI-ACE Project)

Federation House Tansen Marg, New Delhi - 110 001

Phone(s) : +91-11-3736190/3312129 • Fax : +91-11-3312170

E-mail : aceindia@giasdl01.vsnl.net.in • Internet : http: //www.milcom.com/ace